

EXHIBIT A

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TOC: **Code of Federal Regulations > /.../ > SUBPART J-- SUBMISSION OF MANUFACTURER'S AVERAGE SALES PRICE DATA > § 414.804 Basis of payment.**

Citation: **42 c.f.r. 414.800**

Section: **42 CFR 414.804**

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***** THIS SECTION IS CURRENT THROUGH THE MAY 20, 2004 ISSUE OF ***
*** THE FEDERAL REGISTER *****

**TITLE 42 -- PUBLIC HEALTH
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH
AND HUMAN SERVICES
SUBCHAPTER B -- MEDICARE PROGRAM
PART 414 -- PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES
SUBPART J -- SUBMISSION OF MANUFACTURER'S AVERAGE SALES PRICE DATA**

42 CFR 414.804

§ 414.804 Basis of payment.

(a) Calculation of manufacturer's average sales price.

(1) The manufacturer's average sales price for a quarter for a drug or biological represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after deducting the types of items and transactions listed in paragraph (a)(2) of this section and excluding sales referenced in paragraph (a)(4) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales referenced in paragraph (a)(4) of this section).

(2) In calculating the manufacturer's average sales price, a manufacturer must deduct the following types of transactions and items:

(i) Volume discounts.

(ii) Prompt pay discounts.

(iii) Cash discounts.

(iv) Free goods that are contingent on any purchase requirement.

(v) Chargebacks and rebates (other than rebates under the Medicaid drug rebate program).

(3) To the extent that data on volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (other than rebates under the Medicaid drug rebate program) are available on a lagged basis, the manufacturer should add the data for the most recent 12-month period available and divide by 4 to determine the estimate to apply in calculating the manufacturer's average sales price for the quarter being submitted.

(4) In calculating the manufacturer's average sales price, a manufacturer must exclude sales

that are exempt from the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act.

(5) The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) Each report must be certified by one of the following:

(i) The manufacturer's Chief Executive Officer (CEO).

(ii) The manufacturer's Chief Financial Officer (CFO).

(iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

HISTORY:

[69 FR 17935, 17938, Apr. 6, 2004]

AUTHORITY:

AUTHORITY NOTE APPLICABLE TO ENTIRE PART:

Secs. 1102, 1871, and 1881(b)(i) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(i)).

NOTES:

[EFFECTIVE DATE NOTE: 69 FR 17935, 17938, Apr. 6, 2004, added Subpart J, effective Apr. 30, 2004.]

NOTES APPLICABLE TO ENTIRE CHAPTER:

[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002.]

NOTES APPLICABLE TO ENTIRE PART:

EDITORIAL NOTE: Nomenclature changes affecting this part appear at 60 FR 50442, Sept. 29, 1995, and 60 FR 53877, Oct. 18, 1995.

[PUBLISHER'S NOTE: For Federal Register citation concerning Part 414 Physician Fee Schedule, see 68 FR 9567, Feb. 28, 2003.]

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